PATENT COOPERATION TREATY

# PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



3

| Applicant's or agent's file reference GM50056 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No. PCT/US00/12104 | International filing date *(day/month/year)* 04 MAY 2000 | Priority date *(day/month/year)* 14 MAY 1999 |
| International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/26; A01N 25/00; A61K 47/00 and US Cl.: 435/25, 183, 189; 514/789 | | |
| Applicant SMITHKLINE BEECHAM CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ~~0~~ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 08 NOVEMBER 2000 | 21 AUGUST 2001 |
| Name and mailing address of the IPEA US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>MANJUNATH RAO<br>Telephone No. (703) 308-0196 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No
PCT/US00/12104

## I. Basis of the report

1. With regard to the **elements** of the international application: *

[X] the international application as originally filed

[X] the description
pages 1-70 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims
pages 71-82 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings
pages 1-20 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3)

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form

[ ] furnished subsequently to this Authority in written form

[ ] furnished subsequently to this Authority in computer readable form

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4 [X] The amendments have resulted in the cancellation of

[X] the description, pages NONE

[X] the claims, Nos NONE

[X] the drawings, sheets~~fig~~ NONE

5 [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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## IV. Lack of unity of invention

1 In response to the invitation to restrict or pay additional fees the applicant has

- [ ] restricted the claims
- [X] paid additional fees
- [ ] paid additional fees under protest
- [ ] neither restricted nor paid additional fees.

2 [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3 This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- [ ] complied with
- [X] not complied with for the following reasons:

Please See Supplemental Sheet.

4 Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report

- [X] all parts
- [ ] the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-17 | YES |
| | Claims | NONE | NO |
| Inventive Step (IS) | Claims | NONE | YES |
| | Claims | 1-17 | NO |
| Industrial Applicability (IA) | Claims | 1-17 | YES |
| | Claims | NONE | NO |

2. citations and explanations (Rule 70.7)

Claims 1-17 lack an inventive step under PCT Article 33(3) as being obvious over EP 0826774 A2, 8-28-1996 (SmithKline Beechem Corporation). Claims 1-17 are drawn to an antagonist that inhibits or an agonist that activates an activity of a polypeptide with amino acid sequence SEQ ID NO:2 or 4 or a polypeptide which is 90% identical to SEQ ID NO:2 or 4, wherein the activity is selected from a number of activities as disclosed in claim 1, one such activity being competitive inhibition by palmitoyl CoA versus crotonoyl CoA, a method of treatment of an individual having the need to inhibit or activate Fab I, a method of treatment of an individual infected with bacteria such as *Staphylococcus aureus, Streptococcus pneumoniae,* a method of inhibiting an activity of Fab I, a method of inhibiting the growth of bacteria such as *Staphylococcus aureus, Streptococcus pneumoniae.*

EP 0826774 A2, 8-28-1996 (SmithKline Beechem Corporation) teaches prokaryotic FAB I polypeptide and DNA encoding such polypeptide and a procedure for producing such polypeptides by recombinant techniques. The reference also discloses methods of utilizing such FAB I for treatment of bacterial infection, agonists and antagonists and their use as a therapeutic agents to treat staphylococcal infections and detection of bacteria. However, the reference does not teach a method of inhibiting the growth of the pathogenic bacteria such as *S.aureus* or *S. pneumoniae.* Using the teachings from the above reference and the high level of knowledge existing in the art of microbiology, it would have been obvious to one of ordinary skill in the art to develop a method of inhibiting the growth of *S.aureus* or *S.pneumoniae.* One of ordinary skill in the art would have been motivated to do so as the above pathogenic bacteria are important from the public health point of view. One of ordinary skill in the art would have a reasonable expectation of success because the above reference provides both polynucleotide and polypeptide sequence which are at least 90% identical to polypeptide sequence with SEQ ID NO:2 or 4 and also provides methods for detection, screening agonists/antagonists and their use. Therefore the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

(Continued on Supplemental Sheet.)

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)



Continuation of Boxes I - VIII

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1 and 9, drawn to an agonist/antagonist.

Group II, claims 2-8 and 10-17, drawn to a method of treatment using the agonist/antagonist.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Agonists/antagonists of Staphylococcal Fab I enoyl-ACP reductase and their use to treat certain conditions are well known in the art. Thus, the inventions when considered as a whole does not contribute over the prior art, see EP 0 826,774 A2 entire document.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack Unity of Invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1. The species are as follows:

See claim 1 for a list of 23 species claimed.

The claims are deemed to correspond to the species listed above in the following manner:

All 23 species- claims 1-3, 5-6, 8-12, 14 and 16.

The following claims are generic: 4, 7, 13, 15 and 17.

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Agonists/antagonists of Staphylococcal Fab I enoyl-ACP reductase and their use to treat certain conditions are well known in the art. Thus, the inventions when considered as a whole does not contribute over the prior art, see EP 0 826,774 A2 entire document.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

---------- NEW CITATIONS ----------

NONE

*FOR THE PURPOSES OF INFORMATION ONLY*

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